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E 2

suspension has dispersity with volume weighted mean particle size from 0.2 micrometers to 5 micrometers, each primary particle is a solid drug particle on to which is adsorbed at least one surface modifying agent of which one is a phospholipid, said matrix-forming agent or agents are present in an amount sufficient to allow drying of said admixture to a solidified suspension without irreversible particle aggregation and/or particle agglomeration or particle growth; then,

- b) drying said admixture to a solidified suspension of said surface stabilized primary particles dispersed and embedded throughout a support matrix of said matrix-forming agent or agents, wherein said matrix dissolves or substantially disperses in a rapid disintegration time when in contact with an aqueous environment to release said surface stabilized primary particles into said aqueous environment as a suspension without irreversible particle aggregation and/or particle agglomeration and without particle size growth; then,
- c) optionally coarse milling and blending said solidified suspension with one or more pharmaceutically acceptable excipients to provide a dried powder; and then,
- d) forming said dried material or said dried powder into a solid dosage form.

2

51. (New) The process of claim 50, wherein the matrix-forming bulking/releasing agent is selected from the group consisting of a pharmaceutically acceptable saccharide, a pharmaceutically acceptable polysaccharide, a pharmaceutically acceptable humectant, a pharmaceutically acceptable cellulose based polymer, combinations thereof, and combinations of these with a pH buffering salt.

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52. (New) The process of claim 50, wherein the matrix-forming bulking/releasing agent is selected from the group consisting of mannitol; trehalose; sorbitol; maltose; combinations thereof; combinations of mannitol, trehalose, sorbitol, and maltose with lactose; combinations of mannitol, trehalose, sorbitol, maltose, and lactose with sucrose; and combinations thereof with a pH buffering salt.

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E 1
H 8
53. (New) The process of claim 50, wherein the matrix-forming bulking/releasing agent is selected from the group consisting of mannitol; trehalose; sorbitol; maltose; combinations of mannitol, trehalose, sorbitol, and maltose with lactose; combinations of mannitol, trehalose, sorbitol, maltose, and lactose with sucrose; microcrystalline cellulose; hydroxymethyl cellulose; hydroxypropyl cellulose; methylcellulose; combinations thereof, and combinations thereof with a pH buffering salt.

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54. (New) The process of claim 50, wherein the matrix-forming agent is present in an amount between 0.1% w/w and 90% w/w.

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55. (New) The process of claim 50, wherein the rapid disintegration time is less than 2 minutes.

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H 9
56. (New) The process of claim 50, wherein the drug is selected from the group consisting of antifungal agents, immunosuppressive agents, immunoactive agents, antiviral agents, antineoplastic agents, analgesic agents, antiinflammatory agents, antibiotic agents, antiepileptic agents, anesthetic agents, hypnotic agents, sedative agents, antipsychotic agents, neuroleptic agents, antidepressant agents, anxiolytic agents, anticonvulsant agents, antagonist agents, neuron blocking agents, anticholinergic agents, cholinomimetic agents, antimuscarinic agents, muscarinic agents, antiadrenergic agents, antarrhythmic agents, antihypertensive agents, hormones, and nutrients.

8
57. (New) The process of claim 50, wherein the drug is selected from the group consisting of fenofibrate, itraconazole, and cyclosporine.

9
sub
H 10
58. (New) The process of claim 50, wherein the drug is present in an amount between 0.1% w/w and 60% w/w.

¹⁰
59. (New) The process of claim 50, wherein the phospholipid is selected from the group consisting of an egg phospholipid, a soybean phospholipid, and combinations thereof.

¹¹
60. (New) The process of claim 50, wherein the phospholipid is selected from the group consisting of hydrogenated phospholipid, partially hydrogenated phospholipid, and combinations thereof.

¹²
61. (New) The process of claim 50, wherein the phospholipid is selected from the group consisting of phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, phosphatidylinositol, phosphatidylglycerol, phosphatidic acid, a lysophospholipid, and combinations thereof.

¹³
62. (New) The process of claim 50, wherein the surface modifier is selected from the group consisting of pharmaceutically acceptable pharmaceutically acceptable nonionic surfactants, pharmaceutically acceptable anionic surfactants, and pharmaceutically acceptable cationic surfactants.

¹⁴
63. (New) The process of claim 50, wherein the surface modifier is selected from the group consisting of casein, gelatin, tragacanth, acacia, and combinations thereof.

¹⁵
64. (New) The process of claim 50, wherein the surface modifier is selected from the group consisting of a pharmaceutically acceptable polyoxyethylene fatty alcohol ether, a sorbitan fatty acid ester, a polyoxyethylene fatty acid ester, a poloxamer, a polaxamine, and combinations thereof.

¹⁶
65. (New) The process of claim 50, wherein the surface modifier is selected from the group consisting of glycerol monostearate, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, and combinations thereof.

#12
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E2
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66. (New) The process of claim 50, wherein the surface modifier is selected from the group consisting of potassium laurate, triethanolamine stearate, sodium lauryl sulfate, an alkyl polyoxyethylene sulfate, sodium alginate, sodium deoxycholate, dioctyl sodium sulfosuccinate, a negatively charged glyceryl ester, sodium carboxymethylcellulose, calcium carboxymethylcellulose, and combinations thereof.

18
67. (New) The process of claim 50, wherein the surface modifier is selected from the group consisting of benzalkonium chloride, cetyltrimethylammonium bromide, lauryldimethylbenzylammonium chloride, and combinations thereof.

sub
#13
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68. (New) The process of claim 50, wherein the surface modifier is present in an amount between 0.5% w/w and 50% w/w.

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69. (New) The process of claim 50, wherein the admixture is dried by spray drying, spray coating, or freeze-drying.

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70. (New) The process of claim 50, wherein the micronized primary particles are prepared in a particle fragmentation process selected from the group consisting of sonication, milling, homogenization, microfluidization, and antisolvent and solvent precipitation.

22
71. (New) The process of claim 50, wherein the pharmaceutically acceptable excipient is a tableting aid for compression, a glidant for hard gelatin encapsulation, an effervescent disintegration agent, a dispersant for a dry powder inhaler, or a combination thereof.

23
72. (New) The process of claim 50, wherein the dosage form is a tablet, a gelatin encapsulation, or a powder.

Cont
E 2
H 14
73. (New) A process for the preparation of a rapidly disintegrating solid dosage form comprising the steps of:

- a) forming an admixture of a stable aqueous homogeneous suspension of micronized surface stabilized primary particles of a water-insoluble or poorly water-soluble drug with a matrix-forming bulking/releasing agent or a mixture of matrix-forming bulking and releasing agents, wherein said stable aqueous primary particle suspension has dispersity with volume weighted mean particle size from 0.2 micrometers to 5 micrometers, each primary particle is a solid drug particle on to which is adsorbed at least one surface modifying agent of which one is a phospholipid, said matrix-forming agent or agents present in an amount sufficient to allow drying of said admixture to a solidified suspension without irreversible particle aggregation and/or particle agglomeration or particle growth; then,
- b) distributing the admixture of step (a) into unit dosage form molds; and then,
- c) freeze-drying said admixture in said unit dosage form molds to a solidified suspension of said surface stabilized primary particles dispersed and embedded throughout a support matrix of said matrix-forming agent or agents, wherein said matrix dissolves or substantially disperses in a rapid disintegration time when in contact with an aqueous environment to release said surface stabilized primary particles into said aqueous environment as a suspension without irreversible particle aggregation and/or particle agglomeration and without particle size growth.

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74. (New) The process of claim ~~73~~, wherein the matrix-forming bulking/releasing agent is selected from the group consisting of a pharmaceutically acceptable saccharide, a pharmaceutically acceptable polysaccharide, a pharmaceutically acceptable humectant a pharmaceutically acceptable cellulose based polymer, combinations thereof, and combinations of these with a pH buffering salt.

sub #15
cont
F2
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75. (New) The process of claim 73, wherein the matrix-forming bulking/releasing agent is selected from the group consisting of mannitol; trehalose; sorbitol; maltose; combinations thereof; combinations of mannitol, trehalose, sorbitol, and maltose with lactose; combinations of mannitol, trehalose, sorbitol, maltose, and lactose with sucrose; and combinations thereof with a pH buffering salt.

27
76. (New) The process of claim 73, wherein the matrix-forming bulking/releasing agent is selected from the group consisting of mannitol; trehalose; sorbitol; maltose; combinations of mannitol, trehalose, sorbitol, and maltose with lactose; combinations of mannitol, trehalose, sorbitol, maltose, and lactose with sucrose; microcrystalline cellulose; hydroxymethyl cellulose; hydroxypropyl cellulose; methylcellulose; combinations thereof, and combinations thereof with a pH buffering salt.

28
77. (New) The process of claim 73, wherein the matrix-forming agent is present in an amount between 0.1% w/w and 90% w/w.

29
78. (New) The process of claim 73, wherein the rapid disintegration time is less than 2 minutes.

sub #16
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79. (New) The process of claim 73, wherein the drug is selected from the group consisting of antifungal agents, immunosuppressive agents, immunoactive agents, antiviral agents, antineoplastic agents, analgesic agents, antiinflammatory agents, antibiotic agents, antiepileptic agents, anesthetic agents, hypnotic agents, sedative agents, antipsychotic agents, neuroleptic agents, antidepressant agents, anxiolytic agents, anticonvulsant agents, antagonist agents, neuron blocking agents, anticholinergic agents, cholinomimetic agents, antimuscarinic agents, muscarinic agents, antiadrenergic agents, antarrhythmic agents, antihypertensive agents, hormones, and nutrients.

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80. (New) The process of claim 73, wherein the drug is fenofibrate, itraconazole, or cyclosporine.

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81. (New) The process of claim 73, wherein the drug is present in an amount between 0.1% w/w and 60% w/w.

33
82. (New) The process of claim 73, wherein the phospholipid is selected from the group consisting of an egg phospholipid, a soybean phospholipid, and combinations thereof.

34
83. (New) The process of claim 73, wherein the phospholipid is selected from the group consisting of hydrogenated phospholipid, partially hydrogenated phospholipid, and combinations thereof.

35
84. (New) The process of claim 73, wherein the phospholipid is selected from the group consisting of phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, phosphatidylinositol, phosphatidylglycerol, phosphatidic acid, a lysophospholipid, and combinations thereof.

36
85. (New) The process of claim 73, wherein the surface modifier is selected from the group consisting of pharmaceutically acceptable pharmaceutically acceptable nonionic surfactants, pharmaceutically acceptable anionic surfactants, and pharmaceutically acceptable cationic surfactants.

37
86. (New) The process of claim 73, wherein the surface modifier is selected from the group consisting of casein, gelatin, tragacanth, acacia, and combinations thereof.

38
87. (New) The process of claim 73, wherein the surface modifier is selected from the group consisting of a pharmaceutically acceptable polyoxyethylene fatty alcohol ether, a

sorbitan fatty acid ester, a polyoxyethylene fatty acid ester, a poloxamer, a polaxamine, and combinations thereof.

cont
E 2 39 24
88. (New) The process of claim 73, wherein the surface modifier is selected from the group consisting of glycerol monostearate, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, and combinations thereof.

40 24
89. (New) The process of claim 73, wherein the surface modifier is selected from the group consisting of potassium laurate, triethanolamine stearate, sodium lauryl sulfate, an alkyl polyoxyethylene sulfate, sodium alginate, sodium deoxycholate, dioctyl sodium sulfosuccinate, a negatively charged glyceryl ester, sodium carboxymethylcellulose, calcium carboxymethylcellulose, and combinations thereof.

41 24
90. (New) The process of claim 73, wherein the surface modifier is selected from the group consisting of benzalkonium chloride, cetyltrimethylammonium bromide, lauryldimethylbenzylammonium chloride, and combinations thereof.

sub #19 42 24
91. (New) The process of claim 73, wherein the surface modifier is present in an amount between 0.5% w/w and 50% w/w.

43 24
92. (New) The process of claim 73, wherein the micronized primary particles are prepared in a particle fragmentation process selected from the group consisting of sonication, milling, homogenization, microfluidization, and antisolvent and solvent precipitation.

44 24
93. (New) The process of claim 73, wherein the dosage form is a tablet.

45 1
94. (New) A dosage form prepared by the process of claim 50.

cont 46 24
57 95. (New) A dosage form prepared by the process of claim 73.
